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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 065391.0001 | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/US05/40029 | International filing date (day/month/year) 04 November 2005 (04.11.2005) | Priority date (day/month/year) 04 November 2004 (04.11.2004) | |
| International Patent Classification (IPC) or national classification and IPC IPC: A61F 5/56(2006.01);A61C 5/14(2006.01);A61M 16/00(2006.01);A62B 18/08(2006.01) USPC: 128/848,859,860,861,200.26,206.29 | | | |
| Applicant CUTLER, HAROLD E. | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 31 August 2006 (31.08.2006) | Date of completion of this report 23 October 2006 (23.10.2006) | | |
| Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | <p>Authorized officer Justine Yu <i>J. Husley</i> Telephone No. (571) 272-3700</p> | | |

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/40029

Box No. I Basis of the report

1. With regard to the language, this report is based on:
 - the international application in the language in which it was filed.
 - a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4(a))
 - international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):
 - the international application as originally filed/furnished
 - the description:

pages 1-11 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
 - the claims:

pages NONE as originally filed/furnished
 pages* NONE as amended (together with any statement) under Article 19
 pages* 12-15 received by this Authority on 31 August 2006 (31.08.2006)
 pages* NONE received by this Authority on _____
 - the drawings:

pages 1-5 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
 - a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. The amendments have resulted in the cancellation of:
 - the description, pages _____
 - the claims, Nos. 2,7,13 _____
 - the drawings, sheets/figs _____
 - the sequence listing (specify): _____
 - any table(s) related to the sequence listing (specify): _____
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages _____
 - the claims, Nos. _____
 - the drawings, sheets/figs _____
 - the sequence listing (specify): _____
 - any table(s) related to the sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/IPEA/409 (Box No. I) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/40029

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--------------------------------|-----|
| Novelty (N) | Claims <u>12 and 14-19</u> | YES |
| | Claims <u>1,3-6 and 8-11</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1,3-6,8-12,14-19</u> | NO |
| Industrial Applicability (IA) | Claims <u>1,3-6,8-12,14-19</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and Explanations (Rule 70.7)

Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:

Claim 1, 3-6, 8-11 lack novelty under PCT Article 33(2) as being anticipated by Bradley (5,626,128).

As to Claims 1 and 6, Bradley discloses an oral device comprising a mouthpiece member (10), a tube member (29), an attachment member (40), and a palate member (22). Further, Bradley discloses the mouthpiece (10) to be tailored to fit the wearer. (Please see column 2, Lines 39-41).

As to Claims 3 and 8, Bradley discloses a cushion member (28) disposed at the second end of the tube member.

As to Claim 4, Bradley discloses the tube member (29) to be inherently adjustable to adequately fit the size of the users mouth.

As to Claims 5 and 10, Bradley discloses the attachment member (40) to be comprised of a resilient material.

As to Claim 9, Bradley discloses a palate member (22) adjustable to fit the size of the users mouth.

As to Claim 11, Bradley discloses the palate member (22) does not extend past the teeth of the user and allows for air to be dispersed through the whole oral cavity of the user.

Claims 12, 14-19 lack an inventive step under PCT Article 33(3) as being obvious over Bradley (5,626,128) in view of Drager (1,592,345).

Supplemental Box

As to Claim 12, Bradley discloses an oral device comprising all the limitations with the exception of a tongue member. However, at the time the invention was made, the use of tongue members in oral devices was well known. Specifically, Drager teaches a tongue member (c1) to adequately provide patient comfort while suppressing the tongue during use of the device. Therefore it would have been obvious to one having ordinary skill in the art to modify the device of Bradley to include a tongue depressor to enable additional patient comfort means.

As to Claim 14, Bradley discloses a cushion member (28) for the purpose of preventing complete jaw closure and endotracheal tube occlusions.

As to Claim 15, Bradley discloses an adjustable palate member (22) made of a resiliently deformable material for the purpose of better conforming to the contours of the user's mouth.

As to Claims 16, the system of Bradley as modified by Drager is discussed in Claim 12, and teaches the tongue member (c1) is made from a spring member and inherently can be adjusted to a length to adequately fit the user's mouth.

As to Claim 17, Bradley discloses the attachment member is made of resilient material for the purpose of allowing the endotracheal tube to be clamped and affixed during periodic adjustments.

As to Claim 18, Bradley discloses the palate member (22) does not extend past the teeth of the users and allows for air to be dispersed through the whole oral cavity of the user.

As to Claim 19, the system of Bradley as modified by Drager is discussed in Claim 12, and teaches a tongue member (c1) does not extend past the teeth of the wearer and allows for air to be dispersed throughout the whole oral cavity. (Please see Figures 1-7)

Claims 1, 3-6, 8-12, 14-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

REPLACEMENT SHEET

CLAIMS

What Is Claimed Is:

1. An oral device comprising:
a mouthpiece member, the mouthpiece member being of a resilient material and individually tailored to fit within the contours of the teeth of a wearer;
a tube member, the tube member being affixed, at a first end, to the mouthpiece member and extending from the mouthpiece member and operable to maintain upward pressure against the soft tissue at the rear of the roof of the mouth of the wearer; and
an attachment member, the attachment member being attached to the mouthpiece member at at least one location and operable to secure the oral device within the oral cavity of the wearer;
whereby the tube member defines an opening, the opening preventing the collapse of the soft tissue of the wearer by allowing for the free transfer of air between the wearer and the environment.

- 2.

3. The oral device of Claim 1, further comprising a cushion member disposed on a second end of the tube member, the second end of the tube member being opposite the first end of the tube member.

4. The oral device of Claim 1, wherein the tube member comprises an adjustable length to adequately fit the size of the mouth of the wearer.

REPLACEMENT SHEET

5. The oral device of Claim 1, wherein the attachment member is comprised of a resilient material.

6. An oral device comprising:

a mouthpiece member, the mouthpiece member being of a resilient material and individually tailored to fit within the contours of the teeth of a wearer;

a tube member, the tube member being affixed, at a first end, to the mouthpiece member and extending from the mouthpiece member towards the soft tissue at the rear of the roof of the mouth of the wearer;

a soft tissue member, the soft tissue member extending from a second end of the tube member and operable to maintain upward pressure against the soft tissue of the wearer, the second end of the tube member being opposite the first end of the tube member; and

an attachment member, the attachment member being attached to the mouthpiece member at at least one location and operable to secure the oral device within the oral cavity of the wearer;

whereby the tube member defines an opening, the opening preventing the collapse of the soft tissue of the wearer by allowing for the free transfer of air between the wearer and the environment.

7.

8. The oral device of Claim 6, further comprising a cushion member disposed on a second end of the tube member, the second end of the tube member being opposite the first end of the tube member.

9. The oral device of Claim 6, wherein the soft tissue member comprises an adjustable length to adequately fit the size of the mouth of the wearer.

REPLACEMENT SHEET

10. The oral device of Claim 6, wherein the attachment member is comprised of a resilient material.

11. The oral device of Claim 6, wherein the palate member does not extend past the teeth of the wearer and allows for air to be dispersed throughout the whole of the oral cavity of the wearer.

12. An oral device comprising:

a mouthpiece member, the mouthpiece member being of a resilient material and individually tailored to fit within the contours of the teeth of a wearer;

a tube member, the tube member being affixed, at a first end, to the mouthpiece member and extending from the mouthpiece member towards the soft tissue at the rear of the roof of the mouth of the wearer;

a soft tissue member, the soft tissue member extending from a second end of the tube member and operable to maintain upward pressure against the soft tissue of the wearer, the second end of the tube member being opposite the first end of the tube member;

a tongue member, the tongue member extending from the second end of the tube member and operable to maintain downward pressure against the tongue of the wearer; and

an attachment member, the attachment member being attached to the mouthpiece member at at least one location and operable to secure the oral device within the oral cavity of the wearer;

whereby the tube member defines an opening, the opening preventing the collapse of the soft tissue of the wearer by allowing for the free transfer of air between the wearer and the environment.

13.

REPLACEMENT SHEET

14. The oral device of Claim 12, further comprising a cushion member disposed on a second end of the tube member, the second end of the tube member being opposite the first end of the tube member.

15. The oral device of Claim 12, wherein the soft tissue member comprises an adjustable length to adequately fit the size of the mouth of the wearer.

16. The oral device of Claim 12, wherein the tongue member comprises an adjustable length to adequately fit the size of the mouth of the wearer.

17. The oral device of Claim 12, wherein the attachment member is comprised of a resilient material.

18. The oral device of Claim 12, wherein the soft tissue member does not extend past the teeth of the wearer and allows for air to be dispersed throughout the whole of the oral cavity of the wearer.

19. The oral device of Claim 12, wherein the tongue member does not extend past the teeth of the wearer and allows for air to be dispersed throughout the whole of the oral cavity of the wearer.

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